MAY - 2 2001

K002817

510(k) Summary of Safety and Effectiveness

Submitter	ELA Medical, LLC 2950 Xenium Lane North Plymouth, MN 55441 Phone: (763) 519-9400 or (800) 352-6466 FAX: (763) 519-9440 or (888) 352-3299
Contact person	Susan Olive Regulatory Affairs Manager
Date of preparation	July 28, 2000
Device trade name	Synetec™
Common or usual name	Holter ECG analysis software
Classification name	Computer, diagnostic, programmable
Predicate devices	Syneview™ (K990727, ELA Medical, Inc.) Elatec (K895806, ELA Medical, Inc.) Vision Premier™ (510(k) number unknown, SPACELABS BURDICK)[3] ROZINN Holter for Windows (K930564, originally from Northeast Monitoring Inc.) Mars (K991786, GE Marquette Medical Systems Inc.)
Device description	Synetec™ is a Holter ECG analysis software application that allows evaluation of Holter recordings obtained with Syneflash™ (Holter ECG recorder approved in the U.S. under 510(k) K990727) and/or a standard tape recorder. Synetec™ is a Microsoft Windows 95/98 and Windows NT (for editing)-based application run on an IBM-compatible personal computer equipped with a flash-card reader and/or tape cassette reader.
Intended use	Synetec™ Holter ECG analysis software is intended to analyze recorded Holter ECG data. The Heart Rate Variability (HRV) option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability of heart rate data. • The HRV option is not intended to produce any interpretation of those measurements or any kind of diagnosis.

[3] Remark: The SPACELABS BURDICK Vision Premier™ is the successor of the BURDICK ALTAIR 8200 (510(k) K945985, Burdick Inc.), which was a predicate device for Syneview.

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	• The measurements produced by the HRV option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms and other diagnostic tests, as well as the professional's clinical judgement. • The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnostic.
Technological characteristics	Synetec™ Holter ECG analysis software uses the same technology as the predicate device, Syneview™.
Test summary	Synetec™ Holter ECG analysis software complies with voluntary standards, as detailed in the submission, Section 9 - Specific standards and guidances. The following quality assurance measures were applied to the development of Synetec™ Holter ECG analysis software, in compliance with ISO 9001/EN 46001 and Quality System Regulation requirements: • Software development outline • Software development procedure • Software requirements • Hazard analysis • Software design document • Verification and validation plan • Validation results summary
Conclusion	The results of these measures demonstrate that Synetec™ Holter ECG analysis software, with HRV option, is safe and effective and performs as well as the predicate device, Syneview™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2001

Ms. Susan Olive
Regulatory Affairs Manager
ELA Medical, LLC
2950 Xenium Lane North, Suite 120
Plymouth, MN 55441

Re: K002817
Trade/Device Name: ELA Synetec Holter ECG Analysis Software
Regulation Number: 21 CFR 870.1425
Regulatory Class: II (two)
Product Code: DQK
Dated: February 2, 2001
Received: February 6, 2001

Dear Ms. Olive:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

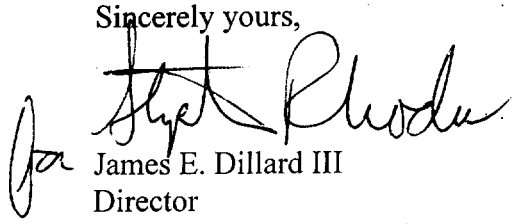
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.10 Indications for Use Statement

510 (k) Number: K002817

Device Name: Synetec™ Holter ECG analysis software.

Indications for Use:

- Analysis of recorded Holter ECG data.
- The Heart Rate Variability (HRV) option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability of heart rate data.
  - The HRV option is not intended to produce any interpretation of those measurements or any kind of diagnosis.
  - The measurements produced by the HRV option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, and other diagnostic tests, as well as the professional's clinical judgement.
  - The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002817

Prescription Use Y OR Over-The-Counter Use _____

(Per 21 CFR 801.109)